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28863 75	590 09/12/2006	EXAMINER		
SHUMAKER & SIEFFERT, P. A.			REIDEL, JESSICA L	
8425 SEASONS PARKWAY			ART UNIT	PAPER NUMBER
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ST. PAUL, MI	N 55125		3766	
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Please find below and/or attached an Office communication concerning this application or proceeding.

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/31/2006.

4) Interview Summary (PTO-413)

Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other:

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#### **DETAILED ACTION**

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on June 28, 2006. Claims 1-59 are pending. Claims 1-18, and 46-59 have been previously withdrawn.

#### Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on March 31, 2006 has been acknowledged and is being considered by the Examiner.

### Claim Objections

3. Claim 33 is objected to because of the following informalities: the language seems awkward. The Examiner suggests revising the first two lines to read "wherein if the processor determines that the patient is not the anticipated patient, the processor determines whether or no the patient". Appropriate correction is required.

#### Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 19, 21, 24-25, 28-29, 34-35, 37, 39 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Cole (U.S. 5,836,993). As to Claims 19, 29, 37 and 42, Cole discloses an external defibrillator 10 comprising an energy delivery system, read as a therapy delivery module 14, and a controller, read as a processor 12 (see Cole Figs. 1 and 12 and column 4, lines 55-65). Cole discloses that the processor 12 may be embodied via a microprocessor, controller, gate

array or other control logic or any combination of such elements (see Cole column 4, lines 62-65). It is inherent that a microprocessor-based processor 12 comprises a computer readable medium comprising the instructions (retrieved from a first memory 16 or a second memory 22) that cause the processor 12 to carry out the disclosed invention.

The processor 12 of Cole determines whether a patient is one of an anticipated patient or a non-anticipated patient and delivers therapy to patient via defibrillator 10 according to a general profile (i.e. the patient is an adult/non-anticipated and the instructions are stored on a first memory 16) or a profile associated with an "anticipated patient" (i.e. the patient is a child and the instructions are stored on a second memory 22) (see Cole column 5, lines 14-27 and lines 66-67 and column 6, lines 1-6). The Examiner takes the position that since a user has to attach the removable memory 22, treating a child or pediatric patient is "anticipated by the user" and thus this type of patient is synonymous with an "anticipated patient". Cole also discloses that the processor 12 determines whether a patient is an "anticipated patient" via actuator 24. Specifically, when the actuator 24 is not actuated, the processor 12 determines that the patient is the not an "anticipated pediatric/child" patient and retrieves instructions for general adult therapy delivery from first memory 16. When a user actuates the actuator 24, upon attachment of the removable second memory 22, the processor 12 determines that the patient is an "anticipated" patient and retrieves instructions for pediatric therapy delivery from the second memory 22.

The "anticipated pediatric/child" patient of Cole is a single patient for receiving therapy by defibrillator 10 - interpreted as Applicant's "individual patient". This "individual patient" is associated with a treatment profile customized and specific to children, therefore the "anticipated pediatric/child individual patient" of Cole is "associated with a patient-specific, customized

profile" (see Cole column 5, lines 28-43 and lines 66-67 and column 6, lines 1-6). Cole specifies, as discussed above that therapy is delivered by the therapy delivery module 14 according to one of a general profile if the patient is the non-anticipated (i.e. adult) patient or the customized profile if the patient is the anticipated patient (i.e. child) (see Cole column 5, lines 14-27 and lines 66-67 and column 6, lines 1-6).

- As to Claims 21 and 39, the Examiner takes the position that since Cole discloses that the second memory 22 contains instructions used by the processor 12 to treat small children (i.e. instructions associated with the anticipated pediatric patient) and that the memory may be a solid state PC card (see Cole column 6, lines 4-6 and lines 47-55), the second memory 22 is synonymous with a patient identification device associated with the anticipated patient. In addition, Cole discloses that the external defibrillator 10 further comprises a port, read as an input circuit 20, and the processor 12 receives an indication from a patient identification device associated with the anticipated patient 22 via the actuator 24 of the input circuit 20 and determines whether the patient is the anticipated patient based on the indication (actuated or not) (see Cole Figs. 1-2 and column 5, lines 28-44).
- As to Claims 24 and 41, Cole discloses that the external defibrillator 10 further comprises a port, read as an input circuit 20, and that the customized profile associated with the anticipated child/pediatric patient is stored within an attachable second memory 22 (see Cole Figs. 1-2 and column 5, lines 28-44). The Examiner takes the position that since Cole discloses that the second memory 22 contains instructions used by the processor 12 to treat small children, the second memory is associated with the anticipated pediatric patient (see Cole column 6, lines 4-6 and lines 47-55). Cole also discloses that processor 12 retrieves the customized profile

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associated with the anticipated child/pediatric patient from the second memory 22 via the input circuit 20 and determines that the patient is the anticipated patient based on receipt (indication from actuation of actuator 24) (see Cole Figs. 1-2 and column 5, lines 28-44).

- 8. As to Claim 25, Cole discloses that the memory 22 associated with the anticipated pediatric patient is a removable medium for the defibrillator 10 (see Cole column 5, lines 17-27).
- 9. As to Claim 28, Cole disclose that the second memory 22 may be disposed at a location remote from device 10 and could communicate the processor's 12 instructions to the device from the remote location through input circuit 20 via a remote connection 48. Cole further discloses that the remove connection 48 may be a network (see Cole column 6, lines 30-46).
- 10. As to Claim 34, the second attachable memory 22 of Cole contains instruction sufficient to operate the device to treat the patient via the anticipated customized pediatric profile (see Cole column 5, lines 28-52 and line 66-67 and column 6, lines 1-6).
- 11. As to Claim 35, the first memory 16 of Cole contains instructions sufficient to operate the device to treat the patient via the general adult profile or non-anticipated patient profile (see Cole column 5, lines 14-27 and line 66-67 and column 6, lines 1-6).

#### Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claims 22, 26-27 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole. As to Claims 22 and 26, Cole discloses the claimed invention as discussed above but does

not expressly disclose the radio frequency identification (RFID) device that is interrogated by the defibrillator 10. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the defibrillator as taught by Cole with the RFID, because Applicant has not disclosed that the RFID provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the PC card as taught by Cole, because it provides a removable memory/patient identification device associated with the anticipated pediatric patient easily interrogated by the defibrillator and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Cole.

Therefore, it would have been an obvious matter of design choice to modify Cole to obtain the invention in as specified in the claim(s).

14. As to Claim 27, Cole discloses the claimed invention as discussed above but does not expressly disclose the that the memory 22 associated with the anticipated pediatric patient comprises a memory within a consumer electronic device. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the defibrillator as taught by Cole with a memory within a consumer electronic device, because Applicant has not disclosed that such a memory provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the PC card as taught by Cole, because it provides a removable memory/patient identification device associated with the anticipated pediatric patient easily interrogated by the defibrillator and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Cole.

Therefore, it would have been an obvious matter of design choice to modify Cole to obtain the invention in as specified in the claim(s).

- 15. Claims 20 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole in view of Snyder et al. (U.S. 6,370,428) (herein Snyder). Applicant differs from Cole in that that processor receives an indication from a user via a user interface and determines whether the patient is the anticipated patient based on the indication. The Examiner considers the use of a user interface for inputting indications that allow a processor to determine the type of patient well known and conventional in the art of external defibrillators with Snyder being but one example (see Snyder Abstract, Fig. 5, column 3, lines 30-67 and column 4, lines 1-38).
- 16. Claims 23 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole in view of Brodard (U.S. 5,285,781). Cole discloses the claimed invention as discussed above except that the second memory 22 does not comprise one of a plurality of anticipated patient profiles each associated with one of a plurality of anticipated patients.

Brodard, however, discloses electrical stimulation apparatuses 2, 50 controlled by detachable and interchangeable information mediums 4, 53, previously programmed as a function of the treatment for each respective patient (see Brodard Abstract, Figs. 1a-1b, column 5, lines 35-42, column 6, lines 13-14 and column 7, lines 18-63). Brodard further discloses that detachable and interchangeable information mediums 4, 53 may be realized in a microchip card having the format of a credit card containing live memories or RAM (see Brodard column 9, lines 40-60). The Examiner takes the position that the electrical stimulation apparatuses of Brodard are analogous with the electrical stimulation apparatus of external defibrillator 10 of Cole since both receive data/memory cards to control their therapeutic outputs. Brodard does not

explicitly state why the detachable and interchangeable information mediums 4, 53, previously programmed as a function of the treatment for each respective patient are used, but it appears that such a detachable and interchangeable information medium is used to personalize the therapeutic output of the stimulation apparatus per patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Cole, with the detachable and interchangeable information mediums previously programmed as a function of the treatment for one of a plurality of patients as taught by Brodard, since such a modification would provide the system with personalized memory cards for providing personalized defibrillation treatment.

17. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cole in view of Rockwell et al. (U.S. 6,141,584) (herein Rockwell). Cole discloses the claimed invention as discussed above except that the external defibrillator 10 is not specified to be an automated external defibrillator (AED).

Rockwell, however, teaches that AEDs can automatically analyze the electrocardiogram (ECG) rhythm of a patient to determine if defibrillation is necessary and thus prompt the responder/user to press a shock button to deliver the defibrillation shock to the patient. Rockwell also discloses that AEDs are designed to be used primarily by first responders who may not be trained in advanced cardiac life support (ACLS) techniques, advancing the versatility of who may use the device to treat a patient (see Rockwell column 1, lines 44-67). It would have been obvious to one having ordinary skill in the art at the time the invention was mode to modify the system of Cole in view of Rockwell to include an AED in order to provide a more user friendly

and versatile external defibrillator that may be used by responders/users not trained in ACLS techniques.

#### Allowable Subject Matter

18. Claims 30-31, 33 and 43-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

the base claim and any intervening claims.

19. Claim 32 would be allowable if rewritten to overcome the Claim Objections, set forth in

this Office action and to include all of the limitations of the base claim and any intervening

claims.

## Response to Arguments

20. Applicant's arguments filed June 28, 2006 have been fully considered but they are not persuasive. In response to Applicant's argument that "Cole does not suggest controlling delivery of therapy to an individual anticipated patient according to an associated patient-specific, customized profile" (see page 13, lines 25-26 of the Remarks), the Examiner respectfully disagrees. The "anticipated pediatric/child" patient of Cole, as discussed above, is a *single* patient for receiving therapy by defibrillator 10 – interpreted as Applicant's "individual patient". This "individual patient" is associated with a treatment profile customized and specific to children, therefore the "anticipated pediatric/child individual patient" of Cole is "associated with a patient-specific, customized profile" (see Cole column 5, lines 28-43 and lines 66-67 and

column 6, lines 1-6). Cole specifies, as discussed above, that therapy is delivered by the therapy

delivery module 14 according to one of a general profile if the patient is the non-anticipated (i.e.

adult) patient or the customized profile if the patient is the anticipated patient (i.e. child) (see Cole column 5, lines 14-27 and lines 66-67 and column 6, lines 1-6).

- In response to Applicant's argument that "there is no suggestion the PC card [of Cole] is 21. a patient identification device that provides an indication of the anticipated patient to a processor" (see page 14, lines 5-7 of the Remarks), the Examiner respectfully disagrees. Cole discloses, as discussed above, that the profile associated with an "anticipated pediatric/child individual patient" is stored on a second memory 22, which when inserted indicates to the processor that the patient is the anticipated pediatric/child individual patient". It is for these reasons that the memory 22 or PC card is synonymous with a patient identification device. Since Cole discloses that the second memory 22 contains instructions used by the processor 12 to treat small children (i.e. instructions associated with the anticipated pediatric patient) and that the memory may be a solid state PC card (see Cole column 6, lines 4-6 and lines 47-55), the second memory 22 is synonymous with a patient identification device associated with the anticipated patient. In addition, Cole discloses that the external defibrillator 10 further comprises a port, read as an input circuit 20, and the processor 12 receives an indication from a patient identification device associated with the anticipated patient 22 via the actuator 24 of the input circuit 20 and determines whether the patient is the anticipated patient based on the indication (actuated or not) (see Cole Figs. 1-2 and column 5, lines 28-44).
- 22. Applicant's Argument, with respect to the rejections of Claims 22 and 26, at page 15 of the Remarks is not found persuasive because Applicant has not *specified why or how* RFID device provides an advantage, has criticality to Applicant's invention and/or *how* it is *not* an arbitrary design consideration [emphasis added]. The Examiner notes that the rejection was not

intended to modify Cole. As stated above, one would have expected Applicant's invention to perform equally well with the PC card as taught by Cole, because it provides a removable memory/patient identification device associated with the anticipated pediatric patient easily interrogated by the defibrillator and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Cole.

#### Conclusion

- 23. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.
- 24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel

Examiner

Art Unit 3766

Robert F. Pezz

Supervisory Patent Examiner

Art Unit 3766